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SFDA Drug Safety communication

Potential Risk of Suicidal Thoughts and Behavior with Fluoroquinolone Antibiotics

Key messages

- The Saudi Food & Drug Authority (SFDA) would like to remind healthcare professionals about the potential risk of psychiatric reactions, including depression, psychosis, and suicidal thoughts or attempts with the use of fluoroquinolone antibiotics.
- SFDA recommends healthcare providers to monitor patients on fluoroquinolones for any new symptoms of psychiatric reactions and advise patients accordingly.
- SFDA is not recommending any changes to the use of fluoroquinolones at this time, but is communicating this information to raise awareness among healthcare providers

Fluoroquinolones, such as ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin, are a type of antibiotics with a broad spectrum of activity. They are commonly used to treat various infections, particularly those affecting the lower respiratory tract caused by Gram-negative bacteria. These antibiotics are also effective in managing exacerbations of chronic obstructive pulmonary disease, broncho-pulmonary infections in individuals with cystic fibrosis or bronchiectasis, and pneumonia.

However, it is important to be aware of a rare safety concern associated with fluoroquinolones, specifically their potential to cause psychiatric reactions that may lead to suicidal thoughts or suicide attempts. This risk has been reported globally, for example, including a recent case where a patient with no prior history of depression or mental health problems died by suicide after being treated with ciprofloxacin. Given the widespread use of fluoroquinolones, it

is crucial for healthcare professionals to monitor patients taking these medications. Patients should be advised to carefully read the information provided in the Patient Information Leaflet regarding potential risks of fluoroquinolones including psychiatric reactions. They also should be advised be vigilant for any changes in mood, distressing thoughts, or feelings related to suicide or self-harm during treatment. If these symptoms occur, medical advice should be sought immediately. It is important to note that fluoroquinolones can worsen existing psychiatric symptoms. Therefore, if any serious adverse reactions, such as new or worsening depression or psychosis, are observed, fluoroquinolone treatment should be discontinued promptly.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>